

NDA 206628/S-005

## **SUPPLEMENT APPROVAL**

HQ Specialty Pharma Corporation  
120 Route 17 North  
Paramus, NJ 07652

Attention: Jeanne Squeglia  
VP Technical

Dear Jeanne Squeglia:

Please refer to your supplemental new drug application (sNDA) dated and received December 12, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dexmedetomidine injection.

This “Changes Being Effected” sNDA provides to add vehicle information to the drug product title for the Prescribing Information and ready to use (bag) presentations, 200 mcg/50 mL (4 mcg/mL) and 400 mcg/100 mL (4 mcg/mL).

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the carton and container labeling, submitted on January 23, 2024, except with the minor revisions listed below as soon as they are available, but no more than 30 days after they are printed.

1. Remove the ‘HCl’ term from the vial presentations to revise the drug product established name to Dexmedetomidine Injection
2. Remove the ‘HCl’ term and “5%” from the bags presentation to revise the drug product established name to Dexmedetomidine Dextrose Injection

We also remind you of your commitment to revise the container and carton labels for both the vial and bag presentations as described above, by updating the PI, container, overwrap (bag only) and carton labeling at next printing, as stated in your June 15, 2023, amendment. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed**”

**Carton and Container Labeling for approved NDA 206628/S-005.** Approval of this submission by FDA is not required before the labeling is used.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.<sup>1</sup>

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.<sup>2</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>3</sup>

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

## **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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<sup>1</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

<sup>2</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>3</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Rachel Jang, PharmD, Regulatory Health Project Manager, at [Rachel.Jang@fda.hhs.gov](mailto:Rachel.Jang@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Rigoberto Roca, MD  
Division Director  
Division of Anesthesiology, Addiction Medicine,  
and Pain Medicine  
Office of Neuroscience  
Center for Drug Evaluation and Research

### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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RIGOBERTO A ROCA  
03/21/2024 10:28:54 AM